UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)
November 16, 2012

DP BARCODE: 404243

MRID : 48872801

SUBJECT: Vital Oxide
(Name of Product)

REG. NO.: 82972-1

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use [ ] OR End-use Product [X]

INGREDIENTS:

PC Code(s)	CAS Number	Active Ingredient(s):
0691545	85409-23-0	Alkyl* dimethyl ethylbenzyl ammonium chloride (*68%C12, 32% C14)
069104	53516-76-0	Alkyl** dimethyl benzyl ammonium chloride (**60% C14, 30% C16, 5% C12, 5% C18)
020503	10049-04-4	Chlorine dioxide

TEST LAB: NA

SUBMITTER: Vital Solutions, LLC

GUIDELINE: NA

ORGANIZATION: AD\PSB\CTT

REVIEWER: Earl Goad

APPROVED BY: Karen P. Hicks

APPROVED DATE: November 16, 2012

COMMENT: Food Use

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November 16, 2012

MEMORANDUM

SUBJECT: Product Chemistry Review for EPA Reg. 82972-1
Product Name: Vital Oxide
DP Barcode: 404243

CODE: (A570) Amendment, Non-fast track

DATE DUE: November 18, 2012

FROM: Earl Goad, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Monisha Harris PM#32/Eliza Blair
Regulatory Management Branch II
Antimicrobials Division (7510P)

12/4/12

Applicant: Vital Solutions,LLC

PRODUCT FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Alkyl* dimethyl ethylbenzyl ammonium chloride (*68%C12, 32% C14)	0.125
Alkyl** dimethyl benzyl ammonium chloride (**60% C14, 30% C16, 5% C12, 5% C18)	0.125
Chlorine dioxide	0.200
Other Ingredient(s):	99.550
Total:	100.000

BACKGROUND:

Laird's Regulatory Consultants, Inc. as the agent for Vital Solutions (aka Vital Technologies) has submitted a formulation change amendment for their product EPA Reg#: 82972-1 "Vital Oxide". The requested change consists of an alternate formulation in which the inert surfactant mixture as found in the basic formulation has been replaced by a different surfactant mixture. It is noted by the registrant that the new surfactant has been DfE approved, is more economical, and less irritating to the eyes.

The product is formulated by a non-integrated process using EPA registered sources of the active ingredients. It is an End Use Product (EUP) disinfectant for residential, commercial & hospital use sites. The product is labeled as performing at a level of 99.999% sanitization of food contact surfaces.

The package is submitted as a PRIA amendment to replace unacceptable surfactants with one (or more) that are both biodegradable and acceptable for use for food contact surface sanitization.

The data package consists of:

1. Letter from the registrant dated June 15, 2012.
2. Formulators Exemption Form (8570-27) dated July 18, 2012.
3. Product label pin-punched June 19, 2012
4. Basic and Alternate Confidential Statements of formula dated May 7, 2012 pin-punched June 19, 2012.
5. MRID# 48872801 Burnett, J. (2012) Vital Oxide: Chemistry. Project Number: CSF. Unpublished study prepared by Vital Solution, LLC. 16p – containing only descriptive data: Copies of basic and alternate CSFs dated May 7, 2012 and an MSDS sheet for the replacement surfactant.

FINDINGS:

1. Both the basic and alternate CSFs dated are consistent with current product labeling regarding nominal concentration of the active ingredients.
2. The new surfactant is acceptable for use in food use according to 40CFR180 sections 910, 930, and 940 for both the basic and alternate formulations.
3. The submitted basic and alternate formulations do have different concentrations of surfactant. The alternate formulation has over three times the concentration of that surfactant than the basic.
4. This product has had some efficacy issues at the time of this review. New efficacy studies that have been submitted have not yet been reviewed. The appropriate confirmatory efficacy must be submitted on both formulations of this product.
5. From the product chemistry perspective, the submitted basic and alternate CSFs are acceptable. However, they may not be marked as acceptable until all efficacy requirements have been completely satisfied.

CONCLUSION:

The basic and alternate formulations dated May 7, 2012 are found to be acceptable as food use under 40CFR 180.940 upon satisfactory completion of review of the confirmatory efficacy for both formulations.